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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,247	01/08/2001	Shubhada D. Godbole	HYS-31CIP	5626

7590
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HYSEQ, INC.
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12/22/2003

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,247

Applicant(s)

GODBOLE ET AL.

Examiner

Marianne P. Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 10-12 and 25 have been elected without traverse in the response submitted 8/23/03.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See at least pages 130 and 135. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Priority

Applicant is requested to update the status of all referenced U.S. patent applications throughout the specification.

Claim Rejections - 35 USC § 112

Claims 10-11 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 10 is directed to a mature protein, an extracellular portion, and an active domain. The specification does not appear to disclose what part of SEQ ID NO: 4 is the mature protein or the extracellular portion. While different signatures or motifs are disclosed for SEQ ID NO: 4,

Art Unit: 1631

these do not appear to be defined as active domains. It is not known from the specification what the active domains of SEQ ID NO: 4 are.

Claims 10-12 and 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 refers to SEQ ID NO: 4 (an amino acid sequence) and the mature protein coding portion thereof and the translated protein coding portion thereof. This is confusing as an amino acid sequence doesn't code for a protein, it is the representation of the protein. It is the translation of the protein encoded by a nucleic acid sequence. Clarification is requested.

Claim 12 requires a polypeptide "having alpha-2-macroglobulin-like activity." It is not known what the metes and bounds of these activities are. Pages 15-16 of the specification discloses biologically active in a very circular fashion without making it clear the particular activities intended to be included and those to be excluded by the claim. In particular, it is unclear what level of similarity of biological activity is required to meet the limitation of the claim.

Claim 25 is directed to a kit comprising the polypeptide of claim 10. This claim is not considered to further limit the subject matter of claim 10 as there are no structural or functional features that differ between the claims. The preamble term "kit" is not considered to clearly impart any structural or functional features.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-12 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimkets et al. (WO 02/29058 A2).

The instant application was filed 08 January 2001 and claims priority to U.S. applications 09/649,167; 09/540,217; 09/684,711; 09/560,875; and 09/496,914. Applicant is denied priority to the filing dates for applications 09/649,167; 09/540,217; 09/560,875; and 09/496,914. There is no apparent basis for SEQ ID NO: 4 nor polypeptides having alpha-2-macroglobulin-like activity in any of these applications.

Applicant is accorded benefit the filing date for application 09/684,711 for claims 10, 11, and 25, but denied benefit for claim 12. There does not appear to be any basis for claiming polypeptides having alpha-2-macroglobulin-like activity comprising at least 20 consecutive amino acids. This length of consecutive amino acids is not contemplated.

As such, claims 10, 11, and 25 have priority to 6 October 2000 and claim 12 has priority to 08 January 2001.

Shimkets et al. discloses SEQ ID NO: 2 (designated NOV1) as an alpha-2-macroglobulin-like protein. See at least pages 11-12 and 16-25. Shimkets et al. was filed 5 October 2001 and claims priority to provisional application 60/238,325 filed 05 October 2000.

Art Unit: 1631

The disclosure relied upon has basis in at least provisional application 60/238,325 filed 05 October 2000.

SEQ ID NO: 2 is an amino acid sequence of length 1492. This sequence is at least 96% identical to SEQ ID NO: 4.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rosen et al. (US 2002/0090672 A1) discloses SEQ ID NO: 583 which is an amino acid sequence of length 531. This sequence has significant similarity to SEQ ID NO: 4, including at least 20 consecutive amino acids. This document is the pre-grant publication for U.S. Patent application 09/764,853, filed 17 January 2001. Priority is claimed to a number of provisional applications. None of these provisional applications appears to be in compliance with the sequence rules and the examiner has been unable to determine if SEQ ID NO: 583 is disclosed in a prior application with an earlier filing date. See attached sequence alignment of SEQ ID NO: 583 and the instant SEQ ID NO: 4. See at least US 2002/0090672 A1 front page, page 37, and pages 367-368.

Rosen et al. (US 2003/0044890 A1) discloses SEQ ID NO: 20 which is an amino acid sequence of length 528. This sequence has significant similarity to SEQ ID NO: 4, including at least 20 consecutive amino acids. This document is the pre-grant publication for U.S. Patent application 09/764,876, filed 17 January 2001. Priority is claimed to a number of provisional applications. None of these provisional applications appears to be in compliance with the sequence rules and the examiner has been unable to determine if SEQ ID NO: 20 is disclosed in

Art Unit: 1631

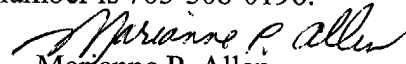
a prior application with an earlier filing date. See attached sequence alignment of SEQ ID NO: 20 and the instant SEQ ID NO: 4. See at least US 2003/0044890 A1 front page, page 37, and pages 367-368.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa